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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/458,779	12/10/1999	MARTIN LATTERICH	1211.001US1	9268

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EXAMINER

LAMBERTSON, DAVID A

ART UNIT PAPER NUMBER

1636

DATE MAILED: 03/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

8M.

# Office Action Summary

Application No.

09/458,779

Applicant(s)

LATTERICH ET AL.

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 3-7,9-12,14-23,25-27,29-34,36-42 and 46-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15,47-50,53 and 54 is/are allowed.
- 6) ☒ Claim(s) 3-7,9-12,14,16-23,25-27,29-34,36-42,46,51 and 52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 December 1999 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed December 12, 2003. Amendments were made to the claims.

Claims 3-7, 9-12, 14-23, 25-27, 29-34, 36-42 and 46-54 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed December 16, 2002, that is not addressed in this action has been withdrawn.

#### *Claim Rejections - 35 USC § 101*

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 4 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. **This rejection is maintained for the reasons set forth in the previous Office Action.**

Applicant's arguments filed December 22, 2003 have been fully considered but they are not persuasive. Applicant contends in their arguments that the rejection 35 USC § 101 is obviated by amendment of the claims. However, it is noted that no amendment has been made to claim 4, thus the rejection cannot be obviated by an absent amendment.

Claim 26 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, since Vff2 is a native yeast gene, the claimed host cell reads on a non-recombinant yeast host cell as it exists in Nature. This lacks the "hand of man"

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and represents non-statutory subject matter. **This is a new rejection that is not necessitated by amendment.**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 5-7, 11, 12, 14, 16-23, 25, 27, 29-34, 36-42 and 46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This rejection is maintained for the reasons set forth in the previous Office Action.**

Applicant's arguments filed December 22, 2003 have been fully considered but they are not persuasive. Applicant provides the following grounds of traversal with regard to the rejection:

1. Applicant argues that there are sufficient teachings regarding nucleotide substitutions that can be made to a polynucleotide sequence without affecting the production of a function protein of page 9, lines 15-27 of the instant specification. Applicant further argues that page 10, lines 11-30 and page 11 provide similar teachings with regards to amino acid substitutions that can be made to a polypeptide sequence without affecting the function of the protein. See for example Applicant's remarks on pages 5-6 of the response entered June 16, 2003.

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2. Applicant asserts that Vff2p exhibits a high degree of homology to proteins in other organisms, and this homology describes a genus of proteins that have a structure-function relationship (i.e., that the homology between these proteins allows the skilled artisan to envision conservative variants of Vff2 protein that necessarily retain the functional activity of the protein). See for example, Applicant's remarks on page 7 of the response entered June 16, 2003.

These arguments are not found convincing for the following reasons:

1. The teachings on both page 9 and page 10-11 provide only generic teachings regarding amino acids that can be substituted for other amino acids. Contrary to Applicant's assertion, there are no specific teachings about Vff2 that indicates which domains of the protein are functional, and which domains can be mutated without consequence to the activity of the protein. While changes such as Asp to Gln, Asn to Gln, or His to Lys (as exemplified on line 21 of page 9 of the instant specification) *may* be made in a protein without affect to the activity of the protein, these changes may also disrupt the catalytic core (or even the active site) of an enzyme or disrupt the structure of a protein such that the protein no longer folds into an active conformation. Without teachings as to which domains of a given protein are necessary and sufficient to provide a structure-function relationship, the skilled artisan cannot envision which residues (i.e., which ones that do not affect these domains adversely) can be changed conservatively.

2. Applicant asserts that there is homology between Vff2 and other genes form organisms such as *S. pombe* (36%), *C. elegans* (24%) and *A. thaliana* (25%). Importantly, there is no indication that these "orthologues" even have the activity that is associated with Vff2.

Thus, the homology between the proteins may be coincidental (i.e., not indicative of a conserved

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function), and thus moot with regard to providing the ability to envision “conservative variants” of Vff2. Furthermore, the ability to predictably envision a structure-function relationship based simply on homology is known to be difficult. This was demonstrated by the conflicting publications of Scott et al. (*Nature Genetics* 21: 440-443, 1999; see entire document; henceforth Scott) and Everett et al. (*Nature Genetics* 17: 411-422, 1997; see entire document; henceforth Everett) regarding the cloning and characterization of PDS. Everett initially identified and sequenced the protein, predicting based upon the sequence that the PDS gene product functioned as a sulphate ion transporter protein because of its similarity to a family of known sulphate ion transporters (see for example the Abstract and page 419, right column, second full paragraph). However, further characterization done by Scott indicated that PDS was not a sulphate ion transporter because it was unable to transport sulphate ions; rather, Scott identified that PDS was a chloride and iodide ion transporter (see for example the Abstract and page 440, the paragraph bridging the left and right columns to the second full paragraph). Scott further indicated that their results underscored the importance of establishing function even in the face of significant homology to proteins of known function (see for example page 441, left column, third full paragraph), thereby establishing that function based on homology is an unpredictable endeavor.

In conclusion, the Written Description rejection is maintained because Applicant has not provided a convincing argument that the skilled artisan can envision “conserved variants” of Vff2. Providing generic teachings of nucleotide/amino acid substitutions that can be made, coupled to limited homology to putative proteins (i.e., there is no clear demonstration that these proteins are actually produced in their respective organisms, as they merely represent Open

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Reading Frames) for which no function has been described is not indicative of the changes that can be made to a protein without affecting the function of the protein.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 9, 10, 31, 33, 37, 51 and 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitation "the encoded protein" in the second line of the claim. There is insufficient antecedent basis for this limitation in the claim because it is unclear if "the encoded protein" is the Vff2 protein, or the heterologous target protein. **This is a new rejection that is necessitated by amendment to the claims.**

Claim 9 recites the limitation "claim 8" in the preamble of the claim as an object of dependency. There is insufficient antecedent basis for this limitation in the claim because claim 8 has been cancelled by amendment. As a result, it is unclear which limitations apply to claim 9. **This is a new rejection that is necessitated by amendment to the claims.**

Claims 31, 33, 37, 51 and 52 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to recite a positive process step that refers back to the preamble of the claim. In order for the claimed method to be definite in terms of the metes and bounds of the invention,

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the claim must recite a method step that provides for the result of the methods as claimed. **This is a new rejection that is not necessitated by amendment to the claims.**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by EMBL entry SCL9476 (cited in the previous Office Action). **This rejection is maintained for the reasons set forth in the previous Office Action.**

Applicant's arguments filed December 22, 2003 have been fully considered but they are not persuasive. Applicant contends in their arguments that the rejection 35 USC § 102(b) is obviated by amendment of the claims. However, it is noted that no amendment has been made to claim 4, thus the rejection cannot be obviated by an absent amendment.

Claims 26 is rejected under 35 U.S.C. 102(b) as being anticipated by Livingstone-Zatchej *et al.* (*Nuc. Acids Res.* **25**: 3795-3800, 1997; see entire document; henceforth Zatchej). **This is a new rejection that is not necessitated by amendment.**

Claim 26 reads on any native yeast cell because *VFF2* (represented by nucleotide SEQ ID NO: 1) is a native yeast gene that is present in all “wildtype” yeast cells. Zatchej teaches at leas



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the wild type yeast strain W303-1a, which naturally comprises the sequence identified as SEQ ID NO: 1. As such, Zatchej anticipates claim 26.

***Allowable Subject Matter***

Claims 15, 47-50, 53 and 54 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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JAMES KETTER  
PRIMARY EXAMINER